

	<p style="text-align: center;">510(k) SUMMARY</p> <p style="text-align: center;"><i>ST360® Spinal Fixation System</i></p>
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Date of Summary Preparation: October 24, 2013

Submitter: Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439

Establishment Registration Number: 2184052

Company Contact: Michelle Lenz
Regulatory Affairs Specialist
Email: Michelle.Lenz@Zimmer.com
Office 952.830.6243
Fax 952.837.6843

Secondary Contact: Jonathan Gilbert
Director of Regulatory Affairs
Email: Jonathan.Gilbert@Zimmer.com
Office: 952.830.6385
Fax: 952.837.6985

Trade Name: ST360® Spinal Fixation System

Device Names: Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease; Orthosis, Spondylolisthesis Spinal Fixation; Orthosis, Spinal Pedicle Fixation; Appliance Fixation, Spinal Interlaminar/Spinal interlaminar fixation Orthosis

Device Classifications: Class III (Class II under 21 CFR 888.3050)

Product Codes: NKB, MNH, MNI, KWP

Regulation Numbers: 21 CFR § 888.3070
21 CFR § 888.3050

Regulation Description: Pedicle screw spinal system

Predicate Devices:

The modified ST360® Spinal Fixation System is substantially equivalent to the legally marketed predicate device, ST360® Spinal Fixation System cleared in K022374, K041925 and K072183.

General Device Description:

The *ST360® Spinal Fixation System* is a temporary implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar and sacral areas of the spine. Implants of this system consist of screws connected to rods and are intended to be removed after solid fusion has occurred. This system includes polyaxial screws of varying diameters and lengths, rods in varying lengths, and fixed and adjustable transverse connectors. The implants in this system are manufactured from titanium alloy (Ti-6Al-4V ELI), conforming to *ASTM F136*.

This system's screws, rods, and connectors can be rigidly locked into a wide range of configurations, thereby allowing each construct to be formed to the needs of an individual patient. The *ST360® Spinal Fixation System* is intended to be used with bone graft which is required to provide additional spinal support.

Indications for Use:

The *ST360® Spinal Fixation System* is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

When used as a sacral screw system, the *ST360® Spinal Fixation System* is intended for use in the treatment of degenerative disc disease (as defined as chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic, deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal fusion. When used for this indication, screws of the *ST360® Spinal Fixation System* are intended for the sacral iliac attachment only. Transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for sacral screw fixation of this system are T1 to the sacrum.

Summary of Technological Characteristics:

Implant Design: Implants of the *ST360® Spinal Fixation System* include polyaxial self-tapping screws of various diameters and lengths; hex end, straight, curved, and top-loading rods of various diameters and lengths, and transverse connectors in both solid and adjustable designs.

Implant Placement: Implants of the *ST360® Spinal Fixation System* are designed for posterior use in the thoracic, lumbar and sacral areas of the spine.

Materials - Implants and Instruments: Implants of the *ST360® Spinal Fixation System* are made from titanium alloy (Ti-6Al-4V ELI). The associated reusable patient-contacting instruments are manufactured from stainless steel that meets the requirements of ASTM A564 / A564M – 10: Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes

Sterility - Implants and Instruments: *ST360® Spinal Fixation System* implants are provided to the end user non-sterile in a poly bag and protective outer box. The associated instruments and perforated instrument cases for use with the *ST360® Spinal Fixation System* implants are also supplied non-sterile. All implants and instruments must be sterilized by the healthcare facility prior to use.

Summary of Performance Testing:

The *ST360° Spinal Fixation System* is substantially equivalent to the predicate devices in design, materials, function and intended use.

The performance testing included components of the subject *ST360° Spinal Fixation System*, which were reviewed and tested appropriately for design verification, design validation, biocompatibility and sterilization. The test results conclude the subject *ST360° Spinal Fixation System* to be substantially equivalent to its predicate device, *ST360° Spinal Fixation System*.

- Bench testing (Static Axial Compression (Bending), Static Torsion, and Axial Compression (Bending) Fatigue per *ASTM F1717-12*; and Static Axial Gripping Capacity, Static Torsion Gripping Capacity, Static Flexion-Extension Gripping Capacity, Static Torsion Gripping Capacity, Static Transverse Moment Gripping Capacity, and Static Axial Torsional Capacity per *ASTM F1798-97 (Reapproved 2008)*) for implants, screws, rods, and connection component, confirmed the product performance of the subject *ST360° Spinal Fixation System* is suitable for its intended use.
- Cadaver lab testing of the subject *ST360° Spinal Fixation System* to evaluate human factors regarding the combination of instrument design changes and labeling design changes, as well as interaction with implants to confirm the substantial equivalence of the changes compared to the identified predicate devices.
- Biocompatibility testing ensured the subject *ST360° Spinal Fixation System* materials are biocompatible after manufacturing based on the minor design changes made in comparison to the predicate devices.
- Sterilization and Dry Time testing ensured the subject *ST360° Spinal Fixation System* steam sterilization, and dry time requirements and instructions are substantially equivalent to the predicate devices.

Substantial Equivalence:

The modified *ST360°® Spinal Fixation System* covered by this submission shares the same technological characteristics as the predicate device, *ST360°® Spinal Fixation System* (K022374, K041925, K072183). Both have the same intended use, operating principle, materials, packaging materials and processes, and substantially equivalent performance characteristics. The indications for use are identical except that references to hooks are being removed from the indications for the modified device, since hooks for this system were never commercialized.

Design verification testing was performed on the modified *ST360°® Spinal Fixation System* in accordance with *ASTM F1717-12*, and *ASTM F1798-97 (reapproved 2008)*. Design validation under simulated use conditions using a cadaver specimen was also performed. The test results confirm that the modified *ST360°® Spinal Fixation System* is substantially equivalent to the predicate device, the *ST360°® Spinal Fixation System* (K022374, K041925, K072183):



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 17, 2013

Zimmer Spine, Incorporated
Ms. Michelle Lenz
Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K133291

Trade/Device Name: ST360°® Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: October 24, 2013
Received: October 25, 2013

Dear Ms. Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Zimmer Spine - 510(k) – ST360® Spinal Fixation System – Indications for Use Statement

Indications for Use

K133291

510(k) Number (if known): _____

Device Name: ST360® Spinal Fixation System

Indications for Use:

The ST360® Spinal Fixation System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

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Prescription Use X

AND/OR

Over-the Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)**Zane W. Wyatt -S**

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K133291